

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-05 /022 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

ARA/EX:KDACKERMAN(INFO)

----- 097691

P 022246Z MAR 76

FM SECSTATE WASHDC

TO AMEMBASSY LA PAZ PRIORITY

AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY SANTO DOMINGO PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY PANAMA PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY MONTEVIDEO PRIORITY

AMEMBASSY CARACAS PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BL, CI, DR, ES, GT, PN,

PE, UY, VE

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-210-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

A. RAVOCAINE HCL 0.4 PERCENT (BRAND OF PROPROXYCAINE HCL)
AND NOVACAIN 2 PERCENT (BRAND OF PROCAIN HCL) WITH NEO-
COBEFRIN 1:20,000 (BRAND OF LEVONORDEFIN). INJECTABLE:
50 CARTRIDGES/CAN. 1.8 AND 2.2 ML. CARTRIDGES; COOK-
WAITE LABS., INC., NEW YORK, NY 10016.

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B. RAVOCAINE HCL 0.4 PERCENT (BRAND OF PROPROXYCAINE HCL)
AND PROCAIN HCL 2 PERCENT WITH NEO-NORDEFIN 1:20,000
(BRAND OF LEVONORDEFIN). INJECTABLE: 50 CARTRIDGES/CAN.
1.8 ML. AND 2.2 ML. CARTRIDGES; WINTHROP LABS., NEW YORK,
NY 10016.

C. CARTUCHO COOK NO. 2 (CLH DE PROPORIZAINA NF 0.4
PERCENT, CLH DE PROCAIN USP 2 PERCENT LEVONORDEFIN, NF
1:20,000). INJECTABLE: 50 CARTRIDGES/CAN, 1.8 ML, AND
2.2 ML. CARTRIDGES; WINTHROP LABS., NEUEVA YORK, NY 10016.

D. CARTUCHO COOK CON CLH DE RAVOCAINE (CLH DE
PROPROXYCAINE NF 0.4 PERCENT); CLH DE PROCAINA USP 2
PERCENT NEO-NORDEFIN (LEVO-NORDEFIN NF, 1:20,000).
INJECTABLES: 50 CARTRIDGES/CAN, 1.8 AND 2.2 ML.
CARTRIDGES; WINTHROP LABS., NUEVA YORK, NY 10016.

LOT NUMBERS:

THESE PRODUCTS HAVE LOT NUMBERS CONSISTING OF THREE
LETTERS FOLLOWED BY TWO DIGITS. ALL LOTS OF CARTRIDGES
WITH AN "L" IN THE SECOND POSITION ARE BEING RECALLED.
ALSO, ALL LOTS WITH THE FOLLOWING COMBINATIONS IN THE
FIRST TWO POSITIONS ARE BEING RECALLED: AN, CN, LN,
PN, RN, UN.

DISTRIBUTION: FROM 1/1/74 UNTIL 8/18/75

MANUFACTURER:

STERLING DRUG, INC.
33 RIVERSIDE AVENUE
RENSSELAER, NY 12144

RECALLING FIRM:

A.
COOK-WAITE LABS., INC.
90 PARK AVENUE
NEW YORK, NY 10016
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B.
WINTHROP PRODUCTS
90 PARK AVENUE
NEW YORK, NY 10016

REASON FOR ADVISORY (RECALL):

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND THAT THERE WAS A QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF "STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MAY ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY MAY TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

- 1) THE SYDNEY ROSS CO. Y CIA (LTDA), SANTIAGO, CHILE (CARTUCHO COOK NO. 2, 1.8 ML. AND RNN, 1.8CC)
- 2) STERLING PRODUCTS INTERNATIONAL INC., SANTO DOMINGO, DOMINICAN REPUBLIC (CARTUCHO COOK WITH RAVOCAINE 1.8 ML)
3. CENTRAL AMERICAN ADMINISTRATION, STERLING PRODUCTS INTERNATIONAL, INC. C.A.A. SAN SALVADOR, EL SALVADOR, C.A. (CARTUCHO COOK WITH RAVOCAINE 1.8 ML)
4. STERLING PRODUCTS, INTERNATIONAL S.A., GUATAMALA CITY, GUATAMALA (CARTUCHO COOK WITH RAVOCAINE 2.2 ML)
5. STERLING PRODUCTS INTERNATIONAL S.A., TEGUCIGALPA, D.C. HONDURAS (CARTUCHO COOK WITH RAVOCAINE 1.8 ML)
6. STERLING PRODUCTS INTERNATIONAL S.A., PANAMA, UNCLASSIFIED

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- REPUBLIC OF PANAMA (CARTUCHO COOK WITH RAVOCAINE 2.2 ML)
7. SYDNEY ROSS, S.A., LIMA PERU, (CARTUCHO COOK WITH RAVOCAINE 1.8 ML) AND FOR BOLIVIA (CARTUCHO COOK WITH RAVOCAINE 1.8 ML)
 8. SYDNEY ROSS, URUGUAY LTDA., MONTEVIDEO, URUGUAY (CARTUCHO COOK WITH RAVOCAINE 1.8 ML)
 9. THE SYDNEY ROSS CO., CARACAS, VENEZUELA (CARTUCHO COOK WITH RAVOCAINE 1.8 ML AND 2.2 ML) INGERSOLL

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NNN

Message Attributes

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Draft Date: 02 MAR 1976
Decaption Date: 01 JAN 1960
Decaption Note:
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Disposition Approved on Date:
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Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: JRWEINROTH, M.D.: AMS
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Executive Order: N/A
Errors: N/A
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Margaret P. Grafeld
Declassified/Released
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04 MAY 2006

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TAGS: OGEN, ETRD, TBIO, BL, CI, DR, ES, GT, PN
To: LA PAZ MULTIPLE
Type: TE
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